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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,226	07/20/2001	H. James Harmon	88142/01-423	3218

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,226

Applicant(s)

HARMON, H. JAMES

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwasa et al., 4,517,290.

Iwasa et al. disclose a method of real-time testing for the presence of an analyte, comprising the steps of: (a) obtaining a colorimetric indicator (see column 9, line 65 – column 10, line 11) that has been reversibly incorporated into a binding protein (see column 10, lines 14-15), said binding protein having an active site and said colorimetric indicator being reversibly bound at said active site; (b) exposing said colorimetric indicator and said binding protein to the sample (see column 13, lines 46-60); (c) determining whether said colorimetric indicator has been displaced from said binding protein by measuring at least one spectral value of said colorimetric indicator and said binding protein (see column 13, lines 61-64); and (d) determining from any spectral value so measured whether or not said analyte is present within said sample (see column 13, lines 61-64, and column 13, lines 4-9.)

As to claim 2, step (a) includes the step of immobilizing said colorimetric indicator and said binding protein on a surface (i.e., the surface of the container holding the reagents, see column 13, lines 46-64.)

As to claim 3, aid colorimetric indicator is porphyrin (see column 10, line 8.)

As to claim 4, said binding protein is AchE (see column 10, line 6.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwasa et al., 4,517,290, in view of Khabashesku et al., 6,428,762.

Iwasa et al. disclose the invention substantially as claimed, except for said surface being a microscope slide. Iwasa et al. teaches the step of measuring the absorbance or intensity of fluorescence of the reaction system to estimate the concentration of an analyte (see column 13, lines 4-9, and lines 61-64.)

Khabashesku et al. also teach the use of spectroscopy for compound analysis, and further disclose use of a microscope slide for spectroscopy (see column 4, line 66 – column 5, line 7.) It would have been obvious to use a microscope slide in the Iwasa et

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al. method when analyzing materials using spectroscopy, as taught by Khabashesku et al.

Claim 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwasa et al., 4,517,290, in view of Chapoteau et al., 5,262,330.

Iwasa et al. disclose the invention substantially as claimed, except for the first of said spectral values being measured at about 402 nm and the other at about 442 nm.

Iwasa et al. disclose examples of enzyme labels (see column 9, line 65 – column 10, line 14.) Iwasa et al. also teach the step of measuring the absorbance or intensity of fluorescence of the reaction system to estimate the concentration of an analyte (see column 13, lines 4-9, and lines 61-64.)

Chapoteau et al. disclose that when reactants form a complex or when a complex dissociates, there is generally an absorbance shift to a different wavelength (see for example column 2, lines 1-6.) Thus, it would have been obvious to measure two spectral values, one being before exposure to a sample, in the Iwasa et al. method since it is well known in the art of spectrophotometry that a shift in wavelength is an indicator of a change in the compounds being analyzed, as taught by Chapoteau et al.

Furthermore, it would have been obvious to measure the two spectral values as claimed, depending on the compounds being analyzed in the assay, (see in Iwasa et al., column 9, line 65 – column 10, line 14 for the various labeling enzymes, and its conjugate protein, see column 13, lines 4-9.)

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Neurath et al., 5,230,998, Althause et al., 6,451,311, and Kobayashi et al, 5,501,988, all disclose use of acetylcholine esterase and porphyrin in an assay. Al-Bayati, 5,68,237, discloses use of acetylcholine esterase as a labeling protein. Wagner et al., 5,741,686, discloses amino acids tagged with porphyrin.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.




LONG V. LE
SUPERVISORY PATENT EXAMINER
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10/01/03